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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,344	09/02/2005	David J. Kyle	026086.033.210 US	1584
24239	7590	09/25/2008	EXAMINER	
MOORE & VAN ALLEN PLLC P.O. BOX 13706 Research Triangle Park, NC 27709			BERTOGLIO, VALARIE E	
		ART UNIT	PAPER NUMBER	
		1632		
		MAIL DATE	DELIVERY MODE	
		09/25/2008	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/532,344	KYLE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Valarie Bertoglio	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 11 September 2008.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-45 is/are pending in the application.

4a) Of the above claim(s) 4-14, 18-33, 37-42, 44 and 45 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-3, 15-17, 34-36, 43 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____ .	6) <input type="checkbox"/> Other: _____ .

**DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/11/2008 has been entered.

No claim has been amended. Claims 1-45 are pending.

This application contains claims 4-14,18-33, 37-42,44 and 45 drawn to an invention nonelected with traverse in the reply filed on 04/19/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-3,15-17,34-36 and 43 are under consideration.

***Claim Rejections - 35 USC § 112-1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3,15-17 and 43 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is maintained for reasons of record set forth at pages 4-6 of the office action dated 06/05/2007.

In summary, the state of the art holds that it is unpredictable whether any particular algae will cause an increase in DHA in shrimp fed the algae and the degree of the increase is also variable. The claims require DHA levels of at least 12.5 ug/g fresh weight of shrimp or a DHA/EPA ratio of at least 2.0.

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Based on the state of the art, only certain feeding conditions would meet these limitations and no feeding conditions have been made of record that lead to a DHA/EPA of at least 2.0. The specification teaches feeding *Cryptocodonium sp.* However, the specification does not teach whether this species of algae results in an increase in DHA to at least 12.5 ug/g fresh weight or the DHA/EPA ratio to at least 2.0. The specification only teaches a modest increase in DHA in 1 out of 2 samples in terms of some percentage relative an unknown standard. It would require undue experimentation to determine how to make the shrimp as claimed comprising at least 12.5 ug/g fresh weight or having a DHA/EPA ratio of at least 2.0 as claimed.

Applicant's arguments have been fully considered and are not found persuasive.

Applicant argues that the specification teaches feeding shrimp a combination of AquaGrow and Zielger shrimp diet. Chromatography of a *lyophilized* 150mg sample of the shrimp after 14 days on the diet was found to comprise, on average 0.34% DHA, which amounts to 510 $\mu$ g/150mg of frozen lyophilized shrimp. Applicant fails to address the aspect of the rejection with respect to the DHA/EPA ration.

This argument is not persuasive. First, the data and calculations are not based on fresh weight, as claimed, and the specification fails to relate lyophilized, frozen weight to fresh weight. Second, as set forth at page 5 of the office action dated 06/05/2007, the specification does not describe to what the data, 0.34%, is in relation. Applicant is arguing that it is in relation to the fresh weight of the shrimp, however, this is not supported by the specification. If in relation to the weight of the shrimp at all, it is in relation to the dry weight. Furthermore, the specification provides only two data points and one data point with the experimental group is identical (0.18%) to the control. Using Applicant's calculation method, the control group would appear to also meet the limitations of the claims. If Applicant were to be persuasive that the experimental diet met the limitations of claim 1, then it is not entirely clear that the control diet and other shrimp diets known in the art would not meet the same limitations.

The rejection is maintained for reasons of record set forth at pages 4-6 of the office action dated 06/05/2007.

*. Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 34-36 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by US 6,451,567 (patent date 09/17/2002, filed 1999).

It is noted that the instant rejection is not in contradiction to the lack of enablement rejection set forth above. The claims are not enabled to the extent that one cannot determine whether the support in the specification correlates to the limitation of at least 12.5 ug/g fresh weight. Similarly, one cannot determine how the dry weight values of the art correlate to the fresh weight values claimed.

Claims 34-36 are drawn to a method of making an organic shrimp comprising feeding microalgal DHA to the shrimp. Claim 35 limits the feeding to use of DHA enriched microalgae and claim 36 specified use of dinoflagellates and chytrids.

The specification teaches increasing the DHA content of shrimp by feeding microalgae. To this extent the following art applies.

‘567 taught feeding multiple algal species, including Schizochytrium. ‘567 taught that such microflora have feed advantages due to its high Omega-3 (DHA) content (see column 2).

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 43 are rejected under 35 U.S.C. 102(a) and (e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US 6,451,567 (patent date 09/17/2002, filed 1999).

It is noted that the instant rejection is not in contradiction to the lack of enablement rejection set forth above. The claims are not enabled to the extent that one cannot determine whether the support in the

specification correlates to the limitation of at least 12.5 ug/g fresh weight. Similarly, one cannot determine how the dry weight values of the art correlate to the fresh weight values claimed.

The claims are drawn to shrimp, raised aquaculturally, comprising DHA at levels higher than about 12.5 ug/g fresh weight (claims 1-3) or comprising a DHA/EPA ratio greater than 2.0 (claims 15-17). Claim 43 is drawn to a shrimp having “high DHA”.

The specification teaches increasing the DHA content of shrimp by feeding microalgae. To this extent the following art applies.

‘567 taught feeding multiple algal species, including Schizochytrium. ‘567 taught that such microflora have feed advantages due to its high Omega-3 (DHA) content (see column 2). Because the shrimps of ‘567 were fed in a manner similar to those of the instant invention, the specification and claims fail to distinguish any identifying characteristics of the shrimp claimed and those of ‘567

It cannot be determined arithmetically that the increased DHA levels measured in terms of total fatty acids correlate to at least 12.5 ug/g fresh weight as claimed, however, in evidence to the contrary, the shrimp of ‘567 and those claimed are structurally identical as they were each fed microalgae.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical means or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. In re Best 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best 562 F.2d sat 1255, 195 USPQ 433. See M.P.E.P 2112.01.

### ***Conclusion***

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Valarie Bertoglio, Ph.D./  
Primary Examiner  
Art Unit 1632